

## **DEPARTMENT OF FOOD AND AGRICULTURE**

Meat, Poultry and Egg Safety Branch

### **INITIAL STATEMENT OF REASONS**

#### **SUBJECT MATTER OF PROPOSED REGULATIONS**

Shell Egg Food Safety

#### **SECTIONS AFFECTED**

Adopt Section 1350. Shell Egg Food Safety  
Amend Section 1354. Marking Requirements

#### **SPECIFIC PURPOSE OF EACH ADOPTION, AMENDMENT, OR REPEAL**

The Department of Food and Agriculture (Department) proposes to adopt section 1350, and amend section 1354 of Subchapter 3, Chapter 1, Division 3, of Title 3 of the California Code of Regulations. The purpose of this proposal is to ensure that eggs are produced in a uniform manner to ensure the quality and safety of shell eggs sold for human consumption by reducing the occurrence of *Salmonella enterica* serotype Enteritidis (SE) contamination of shell eggs during egg production.

This proposal would require any person registered with the Department to engage in business in California as an egg producer or egg handler, and any out-of-state egg handler or egg producer selling eggs in California to (1) implement SE reduction measures consistent with state and federal requirements; (2) comply, within a commercially reasonable time frame, with a minimum numeric enclosure requirement for egg-laying hens if the eggs produced from those hens are sold in California; and (3) comply with specified egg container label requirements to include an affirmative label statement on every package of shell eggs that are for sale in California, certifying that those eggs were sold in compliance with these standards.

Existing law, section 27521 of the Food and Agricultural Code, authorizes the Department to assure that healthful and wholesome eggs of known quality are sold in this state; to facilitate the orderly marketing of shell eggs in a uniform manner; and to prevent the marketing of deceptive or mislabeled containers of eggs.

Existing law, section 27531 of the Food and Agricultural Code, authorizes the Department to adopt regulations relating to the preparation for market and marketing of shell eggs as determined to be reasonably necessary to carry out the purposes of Chapter 1, Part 4, Division 12 of the Food and Agricultural Code.

Existing law, section 27533 of the Food and Agricultural Code specifies that regulations adopted pursuant to Chapter 1, Part 4, Division 12 relating to egg shell surveillance inspection shall be consistent with any federal standards or procedures promulgated by the United States Department of Agriculture on that subject.

Existing law, section 27573 of the Food and Agricultural Code established an advisory committee to the Secretary of the Department on all matters pertaining to standards for shell eggs, the quality of shell eggs; recommendations concerning sampling; uniformity of inspection; adjustment of fees for proper administration and enforcement; annual budget for the

administration and enforcement of the chapter and all matters pertaining to this chapter or regulations adopted pursuant thereto; and, components of the Egg Quality Assurance Plan, a voluntary food safety program, that are consistent with and promote the purposes of the chapter.

Existing law, section 27637 of the Food and Agricultural Code specifies that it is unlawful for a person to make any false, deceptive, or misleading statements concerning the quality, size, weight, condition, source, origin, or any other matter relating to eggs.

Existing law, section 27541 of the Food and Agricultural Code specifies that any person engaged in business in California as an egg producer or egg handler, or any out-of-state egg handler or egg producer selling eggs into California, shall register with the Department. A producer is defined in section 27510.1 of the Food and Agricultural Code to mean a person engaged in the business of producing eggs from domesticated fowl for human consumption.

In accordance with the above-noted sections of law, the Department has in place existing regulations specifying the requirements for persons marketing eggs in California under Subchapter 3, Chapter 1, Division 3, of Title 3 of the California Code of Regulations.

The Department is proposing amendments to the requirements for the marketing of eggs in California by adopting section 1350 (shell egg food safety) and amending section 1354 (marking requirements) of Subchapter 3, Chapter 1, Division 3 of Title 3 of the California Code of Regulations. The intent of this proposal is to ensure that eggs are produced in a uniform manner to ensure the quality and safety of shell eggs sold for human consumption.

Based on an initial evaluation, the Department does not believe the proposed regulations are inconsistent or incompatible with existing state or federal regulations.

### **PROBLEMS INTENDED TO ADDRESS**

The Department is intending to address the problem of the occurrence of *Salmonella enteritidis* (SE) contamination of shell eggs during egg production.

SE is among the leading bacterial causes of food borne illness in the United States, and shell eggs are a primary source of human SE infections. All people are at risk for Salmonellosis, although the severity of the infection is influenced by a person's age and immune status. Most healthy people recover without antibiotic treatment; however, the gastro-intestinal problems can be severe, and hospitalization may be required. In some patients, the infection can become systemic and spread to the blood and other organ systems. Severe complications including death are more likely to occur in children, the elderly, and persons with a weakened immune system.

In May 2010, the Center for Disease Control (CDC) received reports of approximately 200 SE cases every week during late June and early July, 2010. This compares to an average of some 50 reports of SE to the CDC each week over the preceding five years. The United States Food and Drug Administration (FDA), CDC and state partners conducted traceback investigations and found many of the shell eggs consumed were from a single firm located in Iowa. In August 2010, the firm conducted a voluntary nationwide recall of shell eggs that it had shipped since May 2010. The eggs from that single firm were sold to distributors and wholesalers in 22 states and Mexico, who then distributed the shell eggs further throughout the country resulting in 380

million of their eggs being recalled under many different brand names. A second firm in Iowa initiated an additional recall of eggs that went to grocery stores, distributors, and wholesalers in 14 states; these entities then distributed the shell eggs further throughout the country. In all, more than 500 million eggs were involved in the nationwide recall<sup>1</sup>. The recall affected eggs shipped to food wholesalers, distribution centers and foodservice companies in California, Illinois, Missouri, Colorado, Nebraska, Minnesota, Wisconsin, Arizona, Texas, Georgia, Washington, Oregon, Nevada, Utah, Arkansas, Oklahoma and Iowa<sup>2</sup>.

Due to the ongoing concerns of SE, several federal regulations related to egg safety at the food service level have been established. However, because eggs remain the primary source of SE infections the FDA has issued its first and only rule that addresses the introduction of SE into the egg during production<sup>3</sup>. Provisions of the Egg Safety Rule [Federal Register; July 9, 2009, Volume 74, Number 130]<sup>4</sup> went into effect July 9, 2010, except producers with 3,000 or more laying hens have a compliance date of July 9, 2012.

On April 1 and 4, 2011<sup>5</sup>, the Department held informational meetings with the public and industry representatives regarding shell egg food safety. The meetings included discussions about California's existing statewide, voluntary pre-harvest food safety program, the California Egg Quality Assurance Program (CEQAP), the new federal ruling for egg safety and related issues.

Following the discussions, it was determined that there was a need for a state shell egg food safety regulatory program consistent with the requirements of the FDA Egg Safety Rule, consistent with the existing voluntary CEQAP, and consistent with existing state regulations.

#### **STATEMENT OF FACTUAL BASIS AND RATIONALE**

The California egg industry plays a significant role in California agriculture, producing about 5 billion eggs per year with approximately 20 million laying hens. Of the 215.7 million cases of California shell eggs produced in 2009, 66.4 million cases were further processed for food service, manufacturing, retail and export; 124.6 million cases went to retail; 18.3 million cases went for food service use; and 6.4 million cases were exported. In value, California egg production is estimated at \$340 million, with total sales generating approximately \$1 billion.

Major production comes from San Diego, San Bernardino and Riverside Counties in Southern California; Merced, Stanislaus and San Joaquin Counties in the Central Valley; and Sonoma County on the North Coast. In 2008, California is a substantial net importer of eggs produced in other states, producing about six percent of the national total of table eggs and consuming about 12 percent, based on population share. At the national level, California is the fifth largest egg producing state, producing about six percent of the national total of table eggs; however, egg consumption in California is nearly 12 percent, based on population share, thus leaving California's egg supply for its own consumers at a deficit. To supplement the State's high demand for table eggs, California processing plants, producers, and wholesalers, must acquire shipments of table eggs from other states, mainly Iowa, Minnesota, Utah, Missouri, and

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<sup>1</sup> Salmonella Enteritidis Outbreak in Shell Eggs, U.S. Food & Drug Administration, November 30, 2010; summary Egg Safety Final Rule, July 7, 2009

<sup>2</sup> FDA Nationwide Recall

<sup>3</sup> FDA Press Release, July 9, 2010, New Final Rule to Ensure Egg Safety, Reduce Salmonella Illnesses Goes Into Effect

<sup>4</sup> Federal Register/Vol. 74, No. 134/Thursday, July 9, 2009/Rules and Regulations

<sup>5</sup> Department of Food and Agriculture meeting agendas, April 1 and 4, 2011

Michigan. Most of these eggs are in liquid form, however approximately one-third of the shell eggs consumed in California are produced out of the State.

This proposal pertains to the Department of Food and Agriculture (Department), Meat, Poultry and Egg Safety Branch, which has in place the Egg Safety and Quality Management (ESQM) program. The ESQM strives to ensure that eggs sold in California are wholesome, properly labeled and of established quality, while maintaining fair and equitable marketing standards in the California egg industry. The ESQM monitors egg quality at production, wholesale, and retail levels, requires persons engaged in the business of marketing eggs in California to be registered, conducts inspections, and provides training to employees of the cooperating local agencies to ensure consistency and uniform application of standards throughout the State. The program partners with various county agricultural commissioners' to perform production, wholesale and retail inspections. The program also enforces and controls the movement of restricted and inedible eggs through the USDA Shell Egg Surveillance Program. The ESQM is entirely industry-funded through mill assessment and registration fees paid by the in-state and out-of-state egg producers, packers, and shippers.

In accordance with Food and Agricultural Code section 27571 the Department has also established an advisory committee to assist the Secretary in the administration of all matters pertaining to standards for shell eggs including egg quality and sampling, inspection, fee adjustment for administrating and enforcement purposes, budget administration, regulation adoption, and voluntary food safety programs (Food and Agricultural Code section 27573). Members of the California Shell Egg Advisory Committee are appointed by and may hold office at the pleasure of the Secretary. At its February 17, 2010 committee meeting, members discussed various issues including the expanded egg container labeling requirement to ensure compliance with specified standards, as described in this proposal<sup>6</sup>.

To further promote egg production in California and product quality and food safety, since 1995 the Department has had in place the California Egg Quality Assurance Program (CEQAP)<sup>7</sup>. CEQAP is a voluntary pre-harvest food safety program designed to ensure product quality and food safety associated with salmonella and chemical residues in eggs. Farm and processing facilities are reviewed annually by the Department's veterinarians to ensure compliance with the program components<sup>8</sup>.

CEQAP was established with the cooperation and participation of the United States Department of Agriculture, California Department of Health Services, United States Food and Drug Administration, California Veterinary Diagnostic Laboratory Service, the University of California Cooperative Extension Service, and the table egg industry. The CEQAP is a comprehensive program with third party oversight. The University of California Cooperative Extension provides ongoing training classes, and each industry participant is required to have a trained supervisor who is in charge of implementing the program. Producers develop a specific flock plan to address chicks, pullets<sup>9</sup>, feed, rodent control, flock health, biosecurity and environmental monitoring for SE.

CEQAP is known as one of America's strictest egg quality programs with requirements more extensive than the egg safety regulations implemented by the FDA. In 1998, the partners who

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<sup>6</sup> Shell Egg Advisory Committee meeting, February 17, 2010

<sup>7</sup> CEQAP brochure

<sup>8</sup> CEQAP Inspection Sheet

<sup>9</sup> Pullet is a hen (female) less than 17 weeks of age that has not begun to lay eggs

developed CEQAP were selected to receive Vice President Al Gore's "Hammer Award" for establishing a program to provide safer eggs for California consumers. The Hammer Award is given to federal employees and their state, local and private sector partners who have advanced the Vice President's National Partnership for Reinventing Government improving service to customers and helping build a better and more cost-effective government. Awards were also given to representatives from FDA, United States Department of Agriculture/Animal and Plant Health Inspection Service, and California Department of Health Services.

In August 2010, the president of the Association of California Egg Farmers stated that the California egg industry has long been focused on food safety, which is why CEQAP was initially developed in 1995. When 508 million Iowa eggs were recalled across the United States, California eggs have been free of *Salmonella* for more than a decade because of CEQAP<sup>10</sup>. On September 7, 2010, the Governor's Office issued a statement that, "For over a decade, California has implemented the California Egg Quality Assurance Program to ensure that eggs produced in California are safe for consumers"<sup>11</sup>.

Therefore, in formulating this proposal, the Department is requiring components from the existing, voluntary California Egg Quality Assurance Program as part of a mandatory shell egg food regulatory program, which is consistent with the FDA Egg Safety Rule, with more stringent requirements, as specified. The intent of this proposal is to prevent the occurrence of SE contamination of shell eggs at production, and to prevent SE contaminated shell eggs from being marketed to California consumers.

The proposal is outlined below.

#### Proposed Adoption of Section 1350. Shell Egg Food Safety.

The Department is proposing to establish a new section to specify shell egg food safety requirements under Subchapter 3, Chapter 1, Division 3, of Title 3 of the California Code of Regulations to prevent occurrences of SE at egg production.

The two most common ways SE can be transmitted to eggs, vertical transfer and horizontal transfer. Vertical transfer means laying hens and pullets ingested SE (most likely from contaminated feed) which translocated from the gastrointestinal tract of affected birds to their reproductive tracts, hence to their developing eggs. Some freshly produced eggs can be contaminated before the shell forms around their contents. An infected hen can lay many eggs without SE and only occasionally lay an egg contaminated with the *Salmonella* bacterium before returning to lay normal, uninfected eggs. Horizontal transfer means SE in the environment (i.e., manure) was exposed and subsequently penetrated the shells of freshly laid eggs. Other factors that may influence horizontal transfer include the sanitation of cages and grounds, heavy rodent populations, and the age of the flock (older flocks are more likely to have SE than younger flocks).

As described, most types of *Salmonella* live in the intestinal tracts of animals and birds and are transmitted to humans by contaminated foods of animal origin. Stringent procedures for cleaning and inspecting eggs were implemented in the 1970s and have made Salmonellosis in

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<sup>10</sup> California Egg Sales Exploding, August 30, 2010

<sup>11</sup> Schwarzenegger: Eat Local, California Eggs are Safe, September 7, 2010

eggs rare. To address the problem of SE contamination in shell eggs, the Department is proposing to establish specified rules and guidelines for egg producers and handlers for the promotion of healthy flocks that are housed in a safe and sanitary environment. This proposal will serve to ensure a safe and healthful food product by the implementation of uniform interstate and intrastate farm and facility egg food safety regulations for flocks located in California, and the eggs produced from flocks located outside the state. The proposed shell egg food safety requirements will further the Department's mission of assuring that healthful and wholesome eggs of known quality are sold in this state and to facilitate the orderly marketing of shell eggs in a uniform manner in accordance with Food and Agricultural Code section 27521.

Subsection 1350(a) specifies that commencing January 1, 2013, any egg producer or egg handler as defined in sections 27510 and 27510.1 of the Food and Agricultural Code shall comply with the requirements of this section, as specified, for flocks with a hatching date after January 1, 2013.

For clarity purposes the Department is providing the statutory citations for the persons who will be required to comply with the requirements of this proposal<sup>12</sup>. The compliance date of January 1, 2013 will provide producers with the time needed to incorporate the Department's SE prevention measures at their facility operations, and ensure flocks after that date have been produced in accordance with the surveillance measures required by this proposal. This date also does not conflict with the FDA Egg Safety Rule [21 CFR Part 118]<sup>13</sup> which is requiring that, effective July 9, 2012, farms with 3,000 or more laying hens to have SE control plans in place, as specified.

Subsection 1350(b) specifies that registered egg producers or handlers with 3,000 or more laying hens whose shell eggs are not processed with a treatment such as pasteurization to ensure safety shall incorporate all of the provisions of this subsection in their facility operations.

The Department is imposing the SE prevention measures for facilities with 3,000 or more laying hens, which is consistent with the FDA Egg Safety Rule. Geographically, commercial egg production in the western United States is concentrated in California, and in the eastern United States is centered in Ohio, Indiana, Iowa, and Pennsylvania. Other States in which major producers are located include Texas, Minnesota, and Georgia. Over 4,000 farm sites have 3,000 or more egg-laying hens, representing 99 percent of all domestic egg-laying hens and accounting for 99 percent of total egg production. There are an additional 65,000 farms with fewer than 3,000 egg-laying hens, accounting for the balance of eggs produced. Producers with fewer than 3,000 layers do not contribute significantly to the table egg market; therefore, imposing any one or all of the restrictions specified in this proposal would have little measurable impact on the incidence of SE while costs to implement or enforce SE control would be prohibitive.

The Department believes imposing these SE prevention measures are consistent with federal standards and necessary to reduce the occurrence of SE in shell eggs that are marketed to California consumers.

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<sup>12</sup> Food and Agricultural Code sections 27510 and 27510.1.

<sup>13</sup> The Egg Safety Rule at a Glance

Subsection 1350(b)(1) references 21 CFR Part 118 to ensure producers implement provisions required by the FDA's "Egg Safety Rule" for the prevention of SE.

For clarity purposes, the Department is referencing 21 CFR Part 118 in this subsection in accordance with Food and Agricultural Code section 27533. As eggs move from the farm to the table, state governments share egg safety responsibilities with the federal government. USDA assumes responsibility for enforcing refrigeration requirements for shell eggs during storage and transportation and the FDA retains overall responsibility for shell egg safety as well as for egg products after they leave the processing plant. The FDA has sole federal authority for regulating food safety on egg farms. They conduct on-farm investigations when an outbreak of food borne illness has been identified. Once the source of an outbreak is determined, FDA requires that eggs from SE-positive flocks be diverted from sale to the public and destroyed or sent to egg breaking plants for pasteurization.

The FDA Egg Safety Rule [21 CFR Part 118] requires many but not all of the prevention activities that were previously adopted through state voluntary quality assurance programs. It requires that pullets must be raised under SE-monitored conditions to reduce the occurrence of SE; producers must implement biosecurity measures for farms and poultry houses; control rodents, flies, and other pests that may spread disease; implement environmental sampling and testing to monitor flock health; clean and disinfect facilities and grounds; refrigerate eggs during transport; sample and test eggs at regular intervals, and maintain current and accurate records of operations. State Egg Quality Assurance Programs (EQAPs) are voluntary programs based on Hazard Analysis Critical Control Point (HACCP) system principles and designed around production, management, and monitoring practices implemented to decrease the risk of *Salmonella Enteritidis* illness. EQAP's have been found to play a major role in the reduction of *Salmonella* illness in the United States.

Therefore, the Department is referencing the Egg Safety Rule, and incorporating components from the California Egg Quality Assurance Program into a statewide shell egg food safety regulatory program, as specified in this proposal.

Subsection 1350(b)(2) requires the implementation of a SE environmental monitoring program and requiring two additional tests than required by the FDA's Egg Safety Rule. The additional tests are: "chick papers" at delivery and at the end of a flock's life cycle.

The Department is requiring shell egg producers to conduct environmental testing for SE at specified intervals in the production cycle of hens as an indicator of whether SE prevention measures are working effectively. This requirement is consistent with the FDA's Egg Safety Rule except for the additional testing of chick papers at delivery and at the end of a flock's life cycle.

Generally, the FDA requires that producers purchase chicks and pullets from hatcheries participating in the National Poultry Improvement Plan (NPIP) "U.S. SE Monitored Program" or equivalent state plan. Chicks are delivered to farm (a truck can have tens of thousands of chicks). When chicks arrive at a facility, the 'chick papers' (the papers that the chicks defecate on during transport) are swabbed with sterile gauze pads. The swabs are sent to a laboratory for analysis to determine if SE is present. If present at this early stage in the bird's life, the flock is typically not used for egg production.

The birds or pullets are raised in a 'brooder' facility for the first 17 weeks of its life. During this time they are vaccinated for several diseases including SE. In accordance with the FDA egg safety rule, the environment (where the birds defecate) is swabbed for SE between 14 and 16 weeks. At approximately 17 weeks the birds are transferred from the brooder facility to a laying house (which can be caged or cage free). By 20 weeks their egg production is typically 'commercial grade' and they are now considered 'laying hens'. The FDA Egg Safety Rule requires the environment to be swabbed for SE between 40 and 45 weeks. If producers decides to 'molt' the birds (molting is a process of shedding old feathers where the birds are taken out of production for several weeks at approximately 70 weeks of age in order to help increase their egg production post-molt) and the environment is swabbed for SE between 4 and 6 weeks post-molt. However, most commercial laying hens are not molted, and the birds are typically removed from production at around 70-80 weeks of age. If molted, most laying hens are kept in production until around 100-110 weeks of age.

The difference in the FDA regulations and this proposal is that the Department is requiring that when chicks are delivered to a farm or facility the chick papers (where the birds defecate) be tested for SE. The reason is SE can be transmitted via the transovarian route, meaning that chicks can be born SE-positive. They may remain infected as pullets and may be placed into poultry houses as layers already carrying SE and then contaminate their eggs and, in addition, pass SE on to other layers within the poultry house.

The Department is also requiring (consistent with the FDA regulations) that the environment where the birds are kept to be swabbed for SE when pullets are 14-16 weeks of age, 40-45 weeks of age, 4-6 weeks post-molt, and just before being taken out of production (which is not required by the FDA regulations). The house where the birds were kept are then cleaned and disinfected and a new laying flock of 17 week-old pullets are placed in that house. Requiring testing for SE in chick papers at delivery and at the end of a flock's life cycle in addition to the environmental testing at specified intervals (consistent with the FDA Egg Safety Rule) is to optimize the likelihood of detecting SE at critical points in the hen's life. The two additional tests required by this proposal will serve to ensure that SE is not brought onto a clean farm and the end of life-cycle test helps the farmer decide what actions to take before bringing new hens into the hen house.

Subsection 1350(b)(3) requires the implementation of a vaccination program.

The Department is requiring that producers implement and maintain a vaccination program to protect against infection with SE, which includes at a minimum two attenuated live vaccinations and one killed or inactivated vaccination, or a demonstrated equivalent SE vaccination program approved by the Department. The Department believes that a vaccination program should be required under this proposal because it is another proactive way to help protect a flock against infections. Vaccination helps to reduce infections in individual chickens, helps to reduce the number of infected flocks and helps minimize the amount of Salmonella shed into the environment. Vaccinating poultry flocks for Salmonella will help reduce the potential risk of human SE outbreaks.

Inactivated vaccines use killed organisms to stimulate the immune system to protect against subsequent infection with live organisms that cause disease. Inactivated vaccines stimulate the development of antibodies, which provide protection to the pullet/hen and reduce the likelihood of systemic infections that can spread SE to the eggs destined for human consumption. Attenuated live vaccines are made from pathogens that are still viable but do not cause disease



so they more closely resemble a natural infection and therefore stimulate a more lasting immunity. All vaccines are approved for use by specific routes and doses, and the instructions are detailed on the product data sheet.

The potential benefits of vaccinating against SE include a reduction in infections and fecal shedding which would result in a reduction in the amount of SE in the laying house environment. While the FDA does not require vaccination of flocks against SE, it found that in a controlled environment vaccines were found to reduce incidence of intestinal colonization and mean number of SE shed in the feces. Further, in a controlled setting, the same vaccines have been shown to reduce the number of SE-positive eggs laid when compared to non-vaccinated controls.

Subsection 1350(c) requires that, commencing January 1, 2015, egg producers, handlers and retailers that market eggs in California must comply with minimum enclosure requirements for egg-laying hens.

Any egg producer, handler, or retailer who markets eggs in California, whether the farm or facility is located in-state or outside California, must register with the Department in accordance with Food and Agricultural Code section 27541<sup>14</sup>. The Department is imposing a compliance date of January 1, 2015 to allow egg producers sufficient time to restructure their facilities. This compliance date also conforms to Health and Safety Code sections 25990, 25991, and 25996<sup>15</sup>, which imposes specified requirements to be implemented by January 1, 2015, by persons marketing eggs in California.

Several states, including California, have enacted laws that are concerned with farm animal welfare via legislative channels or as a result of a ballot initiative<sup>16</sup>. While the majority of these laws require that farm animals be given a certain amount of space, others reserve the right to make those rules either to the state legislature or to a board put into place to address those issues. As a result of the wide variety of statutes, the statutory language contained in each state differs. While research in this area is ongoing and evolving, the Department believes that the specified minimum enclosure standards are consistent with sections 25990 and 25991 of the Health and Safety Code, and consistent with the Department's proposed SE surveillance and control measures to reduce the incidence of egg contamination associated with SE.

Subsections 1350(c)(1) and (c)(1)(A) proposes to establish minimum cage size enclosures for each egg-laying hen in facilities that market eggs in California whether that facility is located in California or in another state or country, regardless of flock size. This subsection also provides a definition of "enclosure" for clarity purposes, to mean any cage, crate, or other structure used to confine egg-laying hens, and requires water and feed must be available without restriction.

Any person who markets shell eggs in California must be registered with the Department and comply with the Department's laws and regulations. The enclosure requirements for egg-laying hens would affect producers, processing plants, and wholesalers who purchase eggs from other sources and includes shell eggs produced in Mexico and shipped into California. It would apply to producers acting as "retailers" and generally apply to the producer selling eggs locally at farmers' markets or company owned retail stores, but would not apply to retail grocery stores as provided by Food and Agricultural Code section 27510, which provides that it does not apply to

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<sup>14</sup> Food and Agricultural Code section 27541

<sup>15</sup> Health and Safety Code sections 25990, 25991 and 25996

<sup>16</sup> Farm Welfare Statutes, excerpts

any purchaser who is a retailer and who does not handle eggs in any capacity, except as a retailer.

The intent of this subsection is to provide minimum enclosure requirements to promote egg production and healthy flocks that are housed in a safe and sanitary environment. The enclosure is to be a size that sufficiently permits desirable or harmless natural behaviors of hens and mitigating less desirable results due to overcrowding or poor hygiene of the flock.

In determining minimum enclosures for egg-laying hens, the natural behavior of hens must be considered. Chickens are social birds and live together in flocks. They have a communal approach to the incubation of eggs and the raising of young. Individual chickens in a flock will dominate others, establishing a "pecking order" with dominant individuals having priority for food access and nesting locations. There are hundreds of breeds of chickens and a variety of enclosure systems available to producers. The breed of chickens that a producer selects for a flock depends upon the purpose for which the chickens are intended, such as, egg laying stock or meat-type birds.

As a general physiological principal, unfavorable or stressful environmental conditions can negatively affect an animal's immune system. Specifically, in birds there are several examples of 'physiological stress' (i.e., as measured by adrenal reactivity, humoral immune response, and specific immune cell ratios) following specific stressors including cage type and activity (Shini, 2003: Physiological Responses of Laying Hens to Alternative Housing Systems, International Journal of Poultry Science, 357-360<sup>17</sup>). Multiple factors such as disease, skeletal and foot health, pest and parasite load, behavior, stress, affective states, nutrition, and genetics influence the level of health of a flock. Although the need to evaluate the influence of these factors on health is recognized, research is still in the early stages with respect to the association between health and welfare of birds. Hens can experience stress in all housing types and no single housing system ranks high on all health parameters. Likewise, no single breed of laying hen is perfectly adapted to all types of housing systems. Management of each system has a profound effect on the stress of the birds in that system; thus, even a housing system that is considered to be superior relative to hen health can have a negative effect on the flock if poorly managed. The right combination of housing design, breed, rearing conditions, and management is essential to optimize hen health and productivity. [*Hen Welfare in Different Housing Systems, 2011, presented by National Poultry Association Inc.*<sup>18</sup>]

Housing space and access to resources such as feed are also critical to the well-being of laying hens. However, data are currently lacking to determine the amount of feeder space needed to ensure that caged hens have adequate access to feed. If individual feeder space allocation is too low, then competition for access to the feeder may induce aggression, thereby disrupting feeding and ultimately leading to poor health, reduced productivity, and even mortality. Reduced feeder space caused poorer feed efficiency, thereby potentially increasing the cost of production, but did not limit feed intake, lower bone mineralization, or cause increased physiological stress in Hy-Line W-36<sup>19</sup> hens housed in shallow conventional cages, suggesting that it did not impair hen health. [*The effect of feeder space allocation on productivity and*

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<sup>17</sup> Shini, 2003: Physiological Responses of Laying Hens to Alternative Housing Systems, International Journal of Poultry Science, 357-360

<sup>18</sup> Hen Welfare in Different Housing Systems, © 2011, Poultry Science Association Inc.

<sup>19</sup> The Hy-Line W-36 white egg strain is the most common type used for egg production. There are also the Hy-Line brown egg strain and the Hy-Line W-98, which is selected for optimal egg mass.

*physiology of Hy-Line W-36 hens housed in conventional cages*<sup>20</sup>, 2009, Poultry Science Association Inc.]

The Department recognizes that hen health can be a complex issue and considered the national and international trend of evolving standards for the health of hens, egg production, and disease control or mitigation, in addition to varied state laws in the United States regarding farm animals or livestock. The Department believes it is reasonable to include minimum cage size requirements in this proposal related to the reduction, control and monitoring of SE in egg-laying hens as part of its mandate to ensure the safety and quality of eggs sold to California consumers in accordance with Food and Agricultural Code section 27521. The enclosure requirement would affect all producers, handlers and retailers marketing eggs in California, regardless of the flock size. Producers, handlers and retailers are defined in Food and Agricultural Code sections 27510, 27510.1 and 27518 for purposes of this section.

In determining specific minimum enclosures for egg-laying hens, the Department worked in conjunction with the University of California, Davis (UCD), Department of Animal Science, to determine the space used by egg-laying hens<sup>21</sup> for particular natural behaviors like wing flapping. The study was conducted by Joy Mench, PhD, Center for Animal Welfare, UC Davis College of Agricultural and Environmental Sciences. Dr. Mench is a professor in the Department of Animal Science and director of the Center for Animal Welfare at UC Davis.

Dr. Mench conducts research on the welfare of animals and has served on numerous committees and boards related to farm and laboratory animal welfare, including the animal welfare advisory committees of the Maple Leaf Farms, the United Egg Producers, McDonald's, Safeway, Humane Certified, and the Food Marketing Institute and the National Council of Chain Restaurants; National Research Council Committees on Animal Biotechnology and the Use of Mammals in Neuroscience and Behavioral Research; the Livestock Welfare Working Group of the World Animal Health Organization (OIE); the UN Food and Agricultural Organization Expert Committee on Capacity Building to Implement Good Animal Welfare Practices; and the Council on Accreditation of the Association for the Assessment and Accreditation of Laboratory Animal Care. She also chaired the revision of the First Revised Edition of the Federation of Animal Science Societies' Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, and has served as a section editor for the Journal of Applied Animal Welfare Science and Animal Welfare. She was president of the International Society for Applied Ethology from 1998-2000, and is currently a scientific advisor to the European Union's Welfare Quality Assurance project and a member of the Broiler Welfare Guidelines Working Group for the OIE. She is the recipient of the Humane Society of the United States Animals and Society Teaching Award (2001), the Poultry Science Association's Poultry Welfare Research Award (2004), and the University of California, Davis Distinguished Scholarly Public Service Award (2007).

In summary, the UCD study used ten mature (approximately 1.5 years of age), well-feathered Hy-Line W-36 hens from the flock housed at the Hopkins Avian Research Facility, as they are the most common type of hen in California for egg production. Each hen was marked with black livestock marker on the top of her head, tip of her tail, top of her toes, and tips of her wings. The hens were placed individually in a 3ft x 3ft floor pen (total area: 1296 in) for up to 1 hour and

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<sup>20</sup> *The effect of feeder space allocation on productivity and physiology of Hy-Line W-36 hens housed in conventional cages*, 2009, Poultry Science Association Inc.

<sup>21</sup> Final Report – CDFA Agreement 09-0854, “Determination of Space Use by Laying Hens” by Joy Mench, Department of Animal Science, University of California, Davis, CA 95616

video recorded for kinematic analysis. They were recorded: 1) standing in a relaxed posture; 2) turning 180 degrees; and 3) wing flapping. A perch was placed in the pen to stimulate the hens to jump up and down and thus to wing flap. Because none of the hens laid down during the test period, space required for lying was determined by recording the hens from above in their individual 18" x 18" (324 in) home cages and superimposing a pre-measured grid over the video recording. The videos of the hens standing, turning, and wing flapping were analyzed for 3-dimensional space use. The average floor space used by the hens was calculated for each behavior using the maximum length and width of the hens. Floor space required for lying was determined by measuring a hen's length from head to tail and her width at the widest cross-section when she was lying down. The estimated amount of floor space required per hen given different group sizes (n) is:  $322 + [(n-1) \times 87.3]/n$ . This equation was used to validate that the space requirements specified in this proposal allow for behavior such as unrestricted movement; wing flapping. The assumption that the space required per hen decreases as group size increases is validated in other studies referenced in UCD's final report.

For example, the space required for free movement of hens in furnished cages (e.g., perches; nesting boxes) demonstrated that larger enclosures were associated with more free movement even if hens were each provided with only slightly more space than their body size. In larger enclosures free space opens up because hens do not use all of the space available to them. Instead, they tend to cluster rather than space evenly, mainly because multiple hens are trying to access particular resources in the enclosure (e.g., water; feed) at the same time. This additional space allows local freedom of movement important for basic behavior patterns such as feeding, stretching, preening and sitting.

The report from UCD also suggested that a variety of different factors can affect how much space hens need and how they use that space. These include genetics, group size, environmental factors (e.g. ambient temperature), hen age, social effects (e.g. group size), and most particularly the resources that are provided in the housing system. For example, space needs will be greater in systems where resources are more widely distributed. If resources are distributed in such a way that vertical movement is required (for example in aviary systems), that can not only impose different space needs but also affect the space that hens use in performing particular behaviors (for example, a hen will need more space to flap her wings during vertical flight than when she is balancing on a perch).

Based on the findings of this study and report, the Department is proposing the following minimum cage size requirements for egg-laying hens: An enclosure containing nine (9) or more egg-laying hens shall provide a minimum of 116 square inches of floor space per bird. Enclosures containing eight (8) or fewer birds shall provide a minimum amount of floor space per bird using the formula  $322 + [(n-1) \times 87.3]/n$ , where "n" equal the number of birds.

<u>Number of Birds</u>	<u>Square Inches per Bird</u>
<u>1</u>	<u>322</u>
<u>2</u>	<u>205</u>
<u>3</u>	<u>166</u>
<u>4</u>	<u>146</u>
<u>5</u>	<u>135</u>
<u>6</u>	<u>127</u>
<u>7</u>	<u>121</u>
<u>8</u>	<u>117</u>

As the number of birds in a single enclosure reaches 60, the space needed per bird levels off at about 92 square inches, for simplicity, the Department proposes using a fixed number if an enclosure houses nine or more birds. The minimum floor space of 116 square inches for hens is consistent with the European Union (EU) Council Directive [1999/74/EC, July 19, 1999<sup>22</sup>] minimum standards. The use of 116 square inches per white hen required in the EU, coupled with the research that supports the 116 square inch requirement has a significant amount of practical and scientific support behind it. At this point there has been very little scientific research and practical experience with larger square inch minimum standards. Consequently, the Department supports the 116 square inch requirement.

Additionally, Dr. Mench does provide discussion in her report of the differences between the brown hen and the white hen, however, white egg-laying hens account for about ninety percent of the hens currently used for egg production in the United States. Therefore, for the purposes of this proposal, the Department is not specifying the type or species of hen per enclosure, but is using the standard of 116 square inches as a minimum size requirement, and specifying a formula in the regulation text for clarity purposes.

To further promote hen health, the Department is requiring that the enclosure containing egg-laying hens shall provide access to drinking water and feed trough(s) without restriction. Since various egg production systems are used in the United States, this requirement is intended to reduce potential stress due to the lack of ability to reach food or water, rather than prescribe specific systems that may not reduce stress in all enclosures. Systems that minimize feces in the feed and water and maintain a dry environment are superior for control of SE, but due to the wide range of poultry housing across the nation, at this time the Department is not specifying specifics on how best to deliver food and water.

The Department believes that establishing minimum enclosure requirements is a necessary component in a proactive, uniform shell egg safety program that is administered in accordance with existing state and federal standards. The intent is to ensure a safe and healthful food product by implementing uniform interstate and intrastate farm and facility egg food safety regulations for flocks located in California, and the eggs produced from flocks located outside the state.

#### Amend Section 1354. Marking Requirements.

Subsection 1354(a) is amended for clarity purposes to establish uniform procedures for tracking where the eggs were produced or distributed by to ensure uniformity with 21 CFR section 101.5.

This subsection adds the phrase that, where eggs are not produced by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such eggs; such as, "Produced for *[to be inserted]* or Distributed by *[to be inserted]*", or any other wording that expresses the facts. This additional language on the label of a container of eggs is necessary for consistency with proposed regulation section 1350 and 21 CFR section 101.5<sup>23</sup>, which uses similar wording for the contents of the label of a food packaged for display or distribution to the consumer, both in California or shipped from another state into California. The Department is also adding an underline to the "size" and "grade" table for style and formatting purposes. The words "Size" and "Grade" appear in the existing text, the Department is only adding the underline effect.

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<sup>22</sup> EU Council Directive 1999/74/EC/July 19, 1999

<sup>23</sup> 21 CFR section 101.5

Subsection 1354(a)(1) contains a minor wording change.

The Department is making a wording change for clarity to ensure registered egg producers or handlers understand that they must comply with both subsections (a)(1) “and” (2) of section 1354.

Subsections 1354(b), (c), (d), and (e) are not included in this proposal as the Department is not proposing any changes to this subsections at this time.

Subsection 1354(f) imposes a new labeling statement on all containers of eggs marketed in California, whether they were produced in-state or outside California.

The Department monitors compliance with official United States standards, grades, weight classes, so forth, by egg packers who do not use the United States Department of Agriculture, Agricultural Marketing Service (USDA/AMS) shell egg grading services pursuant to Food and Agricultural Code section 27532. Egg cartons from these plants will bear a grade mark however without the USDA shield.

The Department is proposing a new labeling statement on egg containers for persons marketing eggs in California. The USDA is only involved in grading eggs, not enforcing label requirements for eggs sold in California. Therefore, the labeling statement on each carton or container of eggs is to indicate how the eggs were produced<sup>24</sup>. The compliance date for this requirement will be January 1, 2015 for consistency with the proposed egg food safety requirements of proposed regulation section 1350. It will also allow companies time to use current packaging inventory and revise labels. The label statement would be applied to the carton of eggs stating that it meets egg food safety standards as established by this proposal. The Department’s Shell Egg Safety and Quality Management (ESQM) program inspectors would conduct a random audit, both in-state and out-of-state, of registrants’ compliance with specified standards in accordance with Food and Agricultural Code section 27680 and Title 3, California Code of Regulations section 1358.4.

Any packed shell eggs that fail to have the required markings will be put off-sale, and regulation section 1354 cited on the non-compliance tag that is used by program inspectors. Food and Agricultural Code section 27641 states, in part, that “...it is unlawful for any person to prepare, pack, place, deliver for sale, load, ship, transport, or sell eggs in the shell unless the eggs and their containers conform to all of the requirements of the chapter or any regulation adopted pursuant to this chapter”. Therefore, the eggs and their containers would be put off-sale if the producer or producer/packer failed to comply with the new regulatory requirements, as proposed.

#### **TECHNICAL, THEORETICAL, AND EMPIRICAL STUDY, REPORT, OR SIMILAR DOCUMENT**

The following studies, reports, documents, and information were relied upon in formulating this proposal:

- 1) Salmonella Enteritidis Outbreak in Shell Eggs, U.S. Food & Drug Administration, November 30, 2010; summary Egg Safety Final Rule, July 7, 2009
- 2) FDA Nationwide Recall

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<sup>24</sup> Sample of egg container label

- 3) FDA Press Release, July 9, 2010, New Final Rule to Ensure Egg Safety, Reduce Salmonella Illnesses Goes Into Effect
- 4) Federal Register/Vol. 74, No. 134/Thursday, July 9, 2009/Rules and Regulations
- 5) Department of Food and Agriculture meeting agendas, April 1 and 4, 2011
- 6) Shell Egg Advisory Committee meeting, February 17, 2010
- 7) CEQAP brochure
- 8) CEQAP Inspection Sheet
- 9) Pullets
- 10) California Egg Sales Exploding, August 2010
- 11) Schwarzenegger: Eat Local, California Eggs are Safe, September 7, 2010
- 12) Food and Agricultural Code sections 27510 and 27510.1
- 13) The Egg Safety Rule at a Glance
- 14) Food and Agricultural Code section 27541
- 15) Health and Safety Code sections 25990, 25991, and 25996
- 16) Farm Welfare Statutes, excerpts
- 17) Shini, 2003: Physiological Responses of Laying Hens to Alternative Housing Systems, International Journal of Poultry Science, 357-360
- 18) *Hen Welfare in Different Housing Systems*, © 2011, Poultry Science Association Inc.
- 19) The Hy-Line W-36 white egg strain is the most common type used for egg production. There are also the Hy-Line brown egg strain and the Hy-Line W-98, which is selected for optimal egg mass.
- 20) *The effect of feeder space allocation on productivity and physiology of Hy-Line W-36 hens housed in conventional cages*, 2009, Poultry Science Association Inc.
- 21) Final Report – CDFA Agreement 09-0854, “*Determination of Space Use by Laying Hens*” by Joy Mench, Department of Animal Science, University of California, Davis, CA 95616
- 22) European Union (EU) Council Directive 1999/74/EC
- 23) 21 CFR section 101.5
- 24) Sample of egg container label
- 25) HR 3798
- 26) Economic Impact Assessment

### **SPECIFIC TECHNOLOGIES OR EQUIPMENT**

This regulation does not mandate the use of specific technologies or equipment. Egg producers and the egg farming industry may prescribe certain standards, technologies, or equipment at their discretion, providing they comply with the minimum standards for egg food safety as specified in this proposal.

### **CONSIDERATION OF REASONABLE ALTERNATIVES**

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Department would either be more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome to affected private persons than the proposed regulation.

Alternatives considered that were rejected:

- 1) Do nothing and rely on the FDA Egg Safety Rule and potential national enclosure legislation to protect California consumers from food borne illness.

The Department rejected this option because the higher food safety standards currently adopted by California egg farmers on a voluntary basis [the California Egg Quality Assurance Program] include critical additional testing for SE and vaccination for salmonella, adding greater food safety assurance for the California consumer.

With regard to enclosures, Congress introduced House of Representatives (HR) 3798<sup>25</sup> January 23, 2012, to provide for a uniform national standard for the housing and treatment of egg-laying hens, under the “Egg Products Inspections Act Amendments of 2012”. Waiting until the enactment of HR 3798 delays the adoption of clear standards potentially for several years and because this legislation has only recently been introduced, the outcome is uncertain. As of this writing, HR 3798 would ultimately propose 124 square inches of floor space per white bird when fully implemented as opposed to the use of 116 square inches per white bird as currently utilized by the European Union (EU). At this point there has been very little scientific research and practical experience with a 124 square inch minimum standard; consequently, the Department supports the 116 square inch requirement for egg-laying hens. The Department believes all three major components (SE surveillance; enclosure requirements; labeling) of this proposal are important to ensure the safety of shell eggs marketed to consumers, and believes a proactive approach is reasonable and necessary to ensure the quality and safety of eggs marketed to California consumers.

2) Enact SE testing and vaccination as proposed and more prescriptive enclosure provisions like those found in the European Union Council Directive 1999/74/EC, July 19, 1999, which was legislation passed on the minimum standards for keeping egg laying hens. The directive, passed in 1999, banned conventional cages in the European Union commencing January 1, 2012 after a 13-year phase-out, and included other various requirements, as specified.

The Department’s minimum cage size requirements are consistent with the EU standard, which requires 116 square inches per white hen. However, the Department is not specifying the type of birds housed, only the minimum cage requirements. Since white egg-laying hens account for about ninety percent of the table eggs in the United States, and a significantly larger percent of birds housed in conventional cages, for simplicity purposes the Department is not specifying the type of hen. The Department also rejected the alternative of providing many detailed mandates, such as, floors, lighting, construction, design of feeding systems, and requirements for cage-free facilities as provided by the EU Directive. The Department believes that building structure design, plans for construction, and various related issues may be considered in future regulatory actions, however, at this time, the Department believes that providing minimum standards for a complete SE surveillance program will form a solid basis for any future regulatory actions based on evolving science and standards of the poultry industry.

**REASONABLE ALTERNATIVES THE DEPARTMENT HAS IDENTIFIED THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESS**

The Department has not identified any alternatives than the proposed regulation that would lessen any adverse impact on small businesses. No adverse impacts to small businesses are anticipated for the labeling requirements under regulation section 1354, as amended by this proposal. There is an exemption for small businesses from the federal egg safety rule and additional environmental testing and vaccination as required by this proposal for facilities housing less than 3,000 hens, as specified. There is no exemption from the enclosure requirements for producers marketing eggs in California, regardless of flock size, but the Department anticipates that most flocks with less than 3,000 hens will not need to make enclosure modifications to meet the proposed enclosure standards.

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<sup>25</sup> HR 3798



## **BENEFITS**

This proposal benefits the health and welfare of the citizens of California by serving to ensure only healthful and wholesome eggs are marketed to consumers in accordance with Food and Agricultural Code section 27521. The benefits mitigate any potential adverse economic impacts identified in this proposal. SE is among the leading bacterial causes of food borne illness in the United States, and shell eggs are a primary source of human SE infections. California consumers and the egg industry would benefit from this proposal because the Department is charged with the mission of assuring that healthful and wholesome eggs of known quality are sold in this state and to facilitate the orderly marketing of shell eggs in a uniform manner in accordance with Food and Agricultural Code section 27521. Monetary benefits would be the potential reduction of the occurrence of SE in shell eggs which could cost the industry millions in recalling contaminated eggs from the marketplace and could lead to illnesses to the public. Nonmonetary benefits would be consumer confidence that comes from knowing that eggs sold in California meet the nation's highest food safety standards and market stability derived from strong food borne illness prevention measures applied equally to all suppliers into California markets and clear labeling of such products.

## **FACTS, EVIDENCE, DOCUMENTS, TESTIMONY, OR OTHER EVIDENCE OF SIGNIFICANT ADVERSE IMPACT ON BUSINESS**

- ***Businesses Impacted:*** Approximately 1,151 registered egg handlers consisting of 10 processing plants, 608 which are both processing plants and producers, 202 wholesalers, and 331 producers.

This proposal requires two additional environmental tests and a SE vaccination program than what is currently required by the federal Egg Safety Rule [21 CFR Part 118]. The Department is calculating the cost of the provisions of this proposal, not the current cost for businesses to comply with existing state or federal regulations, or the cost to existing businesses that participate in the voluntary California Egg Quality Assurance Program for SE control, or the cost of the space requirements specified in Health and Safety Code sections 25990 and 25991 for egg-laying hens.

### ***Estimated costs to businesses to comply with the SE prevention measures by January 1, 2013:***

There are approximately 1,279 farms in California that produce eggs, of that total, the majority of the eggs are produced from 150 farms represented by 28 companies. Nationally, there are approximately 5,098 farms and a majority of those eggs produced are from 69 farms. There are approximately 20 million hens in California and 14 million out-of-state that produce eggs sold in California. Out-of-state facilities contribute about 40% of all eggs sold in California.

- Testing of chick papers at delivery for about 8,000-30,000 chicks total about \$35 per truck (a farm can receive about 100,000 chicks per delivery)
- The cost for SE control and surveillance is about \$0.12 cents per hen (11 cents for vaccination and one cent for environmental testing)
- Annual costs of SE environmental testing and vaccination are approximately \$1,413,320 for producers

***Costs to businesses to implement the minimum enclosure size requirements for egg-laying hens by January 1, 2015:***

The implementation date of January 1, 2015 was set to avoid conflict with Health and Safety Code section 25996. The space requirements specified in this proposal were set to be consistent with the EU standard, but do not conflict with Health and Safety Code sections 25990 and 25991. Therefore, enclosure requirements of this proposal impose minimal to non-existent additional costs to businesses and are not included in the cost impacts to businesses. It is not the intent of the Department to capture costs already imposed by other state or federal laws or regulations.

The businesses impacted by the enclosure requirements are: Approximately 1,279 farms in California produce eggs, of that total, the majority of the eggs are produced from 150 farms represented by 28 companies. Nationally, there are approximately 5,098 farms and a majority of those eggs produced are from 69 farms. There are approximately 20 million hens in California and 14 million out-of-state producing eggs sold in California. Out-of-state facilities contribute about 40% of all eggs sold in California.

- The Department has made an initial determination that there are no adverse economic impacts to businesses to comply with the labeling requirements under section 1354 as amended by this proposal, in regards to adding specified wording or statements to existing labels on all containers of eggs sold in California.
- *Registration costs:* There are existing application and registration fees in statutes or regulations; however, no new registration fees are imposed by this proposal.
- *Paperwork/Reporting:* There are no new reporting requirements under this proposal. The Department is proposing an expanded labeling statement on containers of all eggs sold in California. It is anticipated any costs associated with the labeling requirements would be negligible, as producers are already complying with specified labeling requirements pursuant to existing regulation section 1354, and the implementation date of January 1, 2015 allows for the depletion of current packaging inventories.
- *Record-keeping:* This proposal may incur additional record-keeping requirements due to the expanded labeling requirement on all containers of eggs to ensure compliance with this proposal, as well as records of environmental testing and vaccinations. However, the records are not required to be sent to the Department. The Department would conduct audits and inspections of facilities to ensure compliance with the requirements as specified in this proposal. Any additional record-keeping costs are anticipated to be negligible since record-keeping is a standard business practice for persons marketing eggs in California.

**RESULTS OF ECONOMIC IMPACT ASSESSMENT:**

The Department of Food and Agriculture (Department) has prepared an economic impact assessment that is included in this filing<sup>26</sup>. The total estimated dollar cost of new provisions required by the Department as a result of this proposal is estimated at \$1,413,320 annually. The Department has made an initial determination that the proposed regulatory action would have

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<sup>26</sup> Economic Impact Assessment

significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation imposes new requirements on shell egg producers and handlers marketing eggs in California. As part of an economic impact assessment, the Department has determined that the proposal will affect the ability of California businesses to compete with other states by making it more costly to produce goods or services, and that it will create or eliminate jobs or occupations. The Department's proposal does not impact multiple industries.

**DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS**

This proposal does not duplicate or conflict with federal regulations. There are related federal regulations concerning disease control and flock management for poultry, under 7 CFR sections 56.76 and 56.77, 9 CFR Parts 56, 145, 146, and 147, and 21 CFR Parts 16 and 118.